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### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.
2. Authorization for this examiner's amendment was given in a telephone interview with Bryan Davidson on September 10, 2008.

The application has been amended as follows:

Canceled claim 10.

Claim 1 (Currently amended) A device for the detection of the presence or absence of an analyte in a fluid sample comprising a backing with a first end (A) and a second end (B) and consecutively going from first end (A) to second end (B):

(a) a sample receiving section attached to one side of the backing at the first end (A) for receiving a test sample;

(b) an analyte detection section attached to said one side of the backing comprising a capture site having binding partners for the analyte immobilized therein;

(c ) an absorption section attached to said one side of the backing;

(d) a reaction section attached to the second end (B) comprising at least one labeling reagents and/or at least one sample pretreatment compounds;

wherein the sample receiving section is in fluid contact with the analyte detection section, which is in fluid contact with the absorption section and wherein there is no fluid contact between the reaction section and any of the other sections.

Claim 2 (Currently amended) The device according to claim 1 wherein the reaction section comprises

- (a) particles bound and/or conjugated to a binding [~~particle~~] partner, and/or
- (b) pre-treatment compounds.

Claim 3 (Currently amended) The device according to claim 1 further comprising a cover member covering part or all of the sample receiving section, the analyte detection section, the absorption section and/or the reaction section.

Claim 4 (Currently amended) The device according to claim 1 wherein the reaction section is located on said one side of the backing or opposite to said one side of the backing or enclosing second end (B) of the backing.

Claim 5 (Twice amended) A method for detecting an analyte in a fluid sample comprising providing [~~a device as in~~] the device of claim 1, and thereafter performing the steps of:

- (a) contacting the reaction section present at the second end (B) of the device with the fluid sample for a period of at least 10 seconds to 10 minutes;
- (b) removing the [reaction section present at the second end (B) of the] device from the fluid sample;

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- (c ) contacting the sample receiving section at the first end (A) of the device ~~[claim 1]~~ with the fluid sample for a period of at least 1 to 10 minutes; and
- (d) detecting the analyte by observing the capture site of the device ~~[claim 1]~~.

Claim 6 (Twice amended)    The method according to claim 5 wherein step (a) comprises using the device to stir the fluid sample ~~[stirring the device]~~.

Claim 7 (Twice amended)    The method according to claim 5 wherein the analyte to be determined is a  $\beta$ -lactam antibiotic.

Claim 8 (Twice amended)    The method according to claim 5 wherein the fluid in which an analyte is to be determined is a fluid obtainable from an animal or human body.

Claim 9 (Twice amended)    A kit ~~[suitable for the determination of an analyte in a fluid]~~ comprising [a] the device according to claim 1 and optionally a thermostatic device ~~[, with the aid of which test samples can be kept at a pre-set temperature]~~.

***Reason(s) for Allowance***

3. The following is an examiner's statement of reasons for allowance: the claims define over the prior art of record, specifically Ullman et al, because the prior art of record fails to teach or make obvious a device comprising a sample receiving section, an analyte detection section, and a fluid absorption section that are in fluid contact with each other and a reaction section comprising at

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least one labeling reagent or a pretreatment reagent that is not in fluid contact with any of the other sections. In use, the reaction section is placed in contact with a sample fluid, and after a time removed from the fluid, and then the sample receiving section is brought into contact with the same sample fluid to allow the analyte and labeled reagent complex, if any, in the fluid to bind to the analyte detection section.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

**4.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Monday -- Thursday from 9:00 a.m. - 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Bao-Thuy L. Nguyen/  
Primary Examiner, Art Unit 1641  
September 10, 2008